

REMARKS

The specification has been amended at page 3 to provide the proper cross reference to a United States Patent, which as noted by the Examiner in the Official Action, is the only way that subject matter may be incorporated by reference. The corresponding United States patent number has been added to the specification to overcome the objection to the specification and this amendment does not introduce new matter into the application.

The Examiner objects to the specification on the alleged basis that essential subject matter is improperly incorporated in the specification by reference to SE 9000028-2, However, there is an issued US Patent corresponding to said SE Patent, viz. US 5,296,243 (cf. paragraph 5 of the Official Action). Thus, the reference to the SE Patent 9000028-2 has been replaced by a reference to the corresponding issued US Patent 5,296,243. Applicants most respectfully submit that incorporation by reference to a United States patent is appropriate and therefore, it is requested that the objection of improper incorporation be withdrawn.

Applicants note the Examiner's comments with respect to "antiseecretory proteins" (ASP) whereas SE 9000028-2 refers to "feed-induced lectins" (FIL). In view of this, the Examiner is of the opinion that the claims are indefinite as to the ASP encompassed thereby. Applicants most respectfully direct the Examiner's attention what actually is stated in US 5,296,243 (Lange. et al.) and corresponding to SE 9000028-2. In the account of the prior art, Lange et al. mention antiseecretory proteins (ASP), with reference to Lange's and Lonnroth's publications from 1984 and 1986, and state that the effect of said known antiseecretory proteins is determined in rat in a so-called "intestinal loop test" (column 1, second paragraph). Further, Lange et al. state that their invention is based on the surprising fact that the addition to the feed of certain sugars and amino acids induces "the formation of ASP-life lectins..." and that "the induced proteins and the naturally appearing ASP-proteins have the same molecular weights and exert similar (i.e. the same) intestinal effects but they differ in their antigenic (antibody-binding) characteristics and their isoelectric point". Furthermore, they differ in their capacity to be attached to certain polysaccharides such as agaroc; like other

lectins they are able to elute from the poly saccharide by use of monosaccharides such as alpha-methyl-D-glucoside or galactose" (column 1, lines 46-58). Further, it is expressly stated by Lange et al. that said new ASP-like proteins which are induced by sugars and amino acids subsequently will be named "feed-induced lectins" (FIL) (column 1, lines 58-60).

Applicants understand that the Examiner has become somewhat confused since in US 5,296,243 Lange et al. refer to ASP but, then in the sense of the known, naturally appearing antiselectory proteins. However, when talking about antiselectory proteins (ASP) in the present application, it is to be understood that said proteins in this context are identical to the "feed-induced lectins" (FIL). A support for this is found, on one hand, in the present application under the headline "State of the Art", where it is stated that "the formation of an antiselectory protein can be stimulated in animals by feeding the animals with feed to which amino acids and/or sugars and/or amides in certain amounts have been added" and, on the other hand, under the headline "Detailed description of the Invention," where it is expressly stated that "it has surprisingly been found that the formation of ASP is stimulated not only by the addition of amino acids and sugars but also by food to which enzymes have been added".

Applicants regret the confusion caused by using, alternately, the terms ASP and FIL but Applicants trust that the explanation given above will clarify the record as to what one of ordinary skill in the art would understand as what is meant by ASP in the context of the present application. The antiselectory proteins (ASP) of the present application and the ASP-like feed-induced lectins (FIL) of US 5,296,243 exert the same intestinal effects and they are determined by the same "intestinal loop test". Applicants most respectfully trust that one of ordinary skill in the art would clearly understand the meaning of the term in the specification and claims and most respectfully request that the rejection of claims 26-41 be withdrawn.

The rejection of claims 26-28, 30 and 31 as being anticipated under 35 USC 102(b) by Johnston (US 5,665,225). This rejection has been carefully considered but is most respectfully traversed.

Applicants wish to direct the Examiner's attention to MPEP § 2131 which states that to anticipate a claim, the reference must teach every element of the claim.

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). "The identical invention must be shown in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). The elements must be arranged as required by the claim, but this is not an *ipsissimis verbis* test, i.e., identity of terminology is not required. *In re Bond*, 910 F.2d 831, 15 USPQ2d 1566 (Fed. Cir. 1990).

Akzo N.V. v. International Trade Comm'n, 808 F.2d 1471, 1 USPQ2d 1241 (Fed. Cir. 1986) (Claims to a process for making aramid fibers using a 98% solution of sulfuric acid were not anticipated by a reference which disclosed using sulfuric acid solution but which did not disclose using a 98% concentrated sulfuric acid solution.).

Applicants most respectfully traverse on the grounds that Johnston teaches that a mixture of soy flour and particularly malted barley, stirred into water, prevents the occurrence of diarrhea in young animals, it is true, but a very important aspect, compared to the presently claimed invention, is not mentioned by the Examiner, viz. that Johnston's method is used for preventing diarrhea caused by allergic reactions to the soy flour.

As is well known, diarrheas result from a variety of causes of which infections are an important causal complex. Elective surgery is another one. Diarrhea is a complicated body response to different agents having different mechanisms of action. It is not at all obvious to the skilled man that a remedy for allergic diarrhea is effective for diarrhea resulting from another cause.

It is well known to use malt. However, there are great technical problems in preparing foodstuff with malt (except for beer) in order for them to be palatable or suitable for industrial methods of preparation. Applicants most respectfully submit that a critical condition for preventing and curing diarrhea conditions, caused by all sorts of agents, not only diarrhea caused by an allergic reaction, is to prepare the food, in accordance with the present invention, so that, upon consumption of the food, the blood

will contain at least 0.5 units of antisecretory proteins per ml. This is a claim limitation which cannot be ignored and is clearly not anticipated in the reference as would be appreciated by one of ordinary skill in the art. This is not obvious from the knowledge of diarrheas. The mechanisms of fluid secretion are more complicated. Consequently, the Applicants are of the opinion that the claims on file are not anticipated by Johnston, for the reasons set forth above. Accordingly, it is most respectfully requested that this rejection be withdrawn.

Applicants have carefully considered the rejection of claims 26-41 as being unpatentable under 35 USC 103(a) over Johnston, in view of Lange et al. and in further view of Robbins et al. and Aspinall et al. This rejection has been carefully considered but is most respectfully traversed.

Applicants wish to direct the Examiner's attention to the basic requirements of a prima facie case of obviousness as set forth in the MPEP. Section 2143 states that to establish a prima facie case of obviousness, three basic criteria first must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine the reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

Section 2143.03 states that all claim limitations must be taught or suggested by the prior art. In re Royka, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). "All words in a claim must be considered in judging the patentability of that claim against the prior art." In re Wilson, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. In re Fine, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988).

It is the Applicant's firm opinion that Johnston, in combination with Lange et al., Robbins et al. and Aspinall et al., does not in any way meet this standard which is necessary to establish a prima facie case of obviousness of the presently claimed

invention. Thus, as stated above, Johnston teaches a method for preventing diarrhea of young animals, caused by an allergic response to soy flour, and can thus, already for that reason, not be combined with the ether references to render obvious the presently claimed invention. Aspinall et al. only show that the amylopectin contained in starch is more affected by the malting of barley than the amylose component that is relatively little degraded. Bobbins et al. have determined the amino acid composition of the proteins of the malts of cereal species and has not determined the composition pattern of free amino acids of the malts. The reason why the amino acid composition is changed during malting is that some amino acids of the proteins are metabolized and, owing to that, the total composition of amino acids of the malted cereal proteins is changed. From this reference, the man skilled in the art cannot conclude how the composition of free amino acids of the malt is changed during malting.

Consequently, it would not have been *prima facie* obvious to a person of ordinary skill in the art, at the time the claimed invention was made, to employ the method of Johnston for preventing diarrhea of young animals, caused by an allergic response to soy flour, in order to regulate the flux of fluid and electrolytes in the intestine of an animal since Aspinall et al. and Robbins et al. do not at all teach the composition of free amino acids of the malt upon malting of the cereals. In re Fritch, 23 USPQ 1780, 1784(Fed Cir. 1992) ("It is impermissible to engage in hindsight reconstruction of the claimed invention, using the applicant's structure as a template and selecting elements from references to fill the gaps."). Thus, the Applicants strongly assert that Johnston cannot be combined with Lange et al., Robbins et al. and Aspinall et al. in order to reject claims 21-41 under 35 U.S.C. 103(a). Accordingly, it is most respectfully requested that this rejection be withdrawn.

The same standard as discussed above applies to the rejection of claims 26-41 be rejected under 35 U.S.C. 103(a) as being unpatentable over Belles et al. and Camburn in view of Witt et al. since this combination of documents is, as firmly asserted by the Applicants, improper. Again, there must be some motivation in the prior art to modify the references to arrive at the claimed invention. This motivation may not be found in Applicants' specification and "obvious to try" is not the standard of obviousness under 35 USC 103.

Bolles et al. teach the preparation of a flaked cereal product having a fiber content, and this is the very purpose of Belles et al. A starch-degrading enzyme is used to degrade the starch of a bran product in order to prepare an edible and palatable flake product. The process of Belles et al, is aimed at gelatinizing the starch fraction.

Camburn teaches solubilization of dietary fibers (an alpha-glucan containing foodstuff) comprising processing a carbohydrate-containing material under severe conditions of mechanical disruption and shear at high screw speed in an extruder. Glucans are known to reduce the cholesterol level in blood but not to normalize abnormal fluid secretion in the intestines. Therefore, Camburn does not add any knowledge of how to prepare a foodstuff for induction of antisecretory proteins in order to achieve such a normalization.

Witt et al. teach the use of the starch-degrading enzymes of the malt to reduce the viscosity of starch pastes by liquefaction. The skilled man cannot, from this reference, draw any conclusions leading to the claimed invention.

Consequently, the combination of Belles et al., Camburn and Witt et al. to support the rejection of claims 26-41 is improper since Applicants cannot understand how the claimed invention, disclosing a method for regulating the flux of fluid and electrolytes in the intestine of an animal by feeding the animal a sufficient quantity of a foodstuff, prepared from cereals having enzymatic activity, so that 1 ml of blood of said animal will contain at least 0.5 units of antisecretory proteins, can be obvious to the skilled man reading Bolles et al., teaching the preparation of a flaked product by using starch degrading enzymes for starch gelatinization, in combination, with Camburn, teaching a mechanical process for solubilizing an alpha-glucan containing foodstuff, and Witt et al., using the starch-degrading enzymes of the malt for liquefaction of starch. Said three references all teach liquefaction or gelatinization of starch in order to obtain edible and palatable cereal products (flakes, dietary fibers) and do not even indicate the use of cereals having enzymatic activity to provide effective amounts of sugars and amino acids to control or govern the formation of antisecretory proteins in the foodstuff so prepared. Accordingly, it is most respectfully requested that this rejection be withdrawn.

In view of the above comments and further amendments to the claims, favorable reconsideration and allowance of all of the claims now present in the application are most respectfully requested.

Respectfully submitted,

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Marked-Up Version Showing Changes Made

IN THE SPECIFICATION:

Please replace the paragraph at page 3, lines 29-33, with the following replacement paragraph.

The amounts and proportions of the malted and non-malted, if any, cereals required to provide the intended effect can easily be established by the skilled man by routine tests where the response to the induction of the food is measured according to the method stated in [SE 9000028-2] United States Patent 5,296,243. Briefly, the method involves measuring a standardized secretion response in the small intestine of the rat.